Fisher Diagnostics

K 052308

8.3 510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Applicant Name:
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MAY 10 2006

Establishment Registration Number: 1181121

Identification of Device:
Device Name: ARCHITECT® Anti-Tg
Proprietary/Trade Name: ARCHITECT® Anti-Tg Immunoassay, ARCHITECT® Anti-Tg Calibrators & Controls
Common Name: Anti-Tg test system
Device Classification: Class II
Governing Regulation: 21 CFR 866.5870, 862.1660, 862.1150
FDA Panel: Immunology, Clinical Chemistry
Product Code: JZO, JJX, JIT

Identification of Predicate Device:
Nichols Advantage Thyroglobulin Autoantibodies Assay (K983992)
Nichols Advantage Chemiluminescence Tri-Level Controls (K972070)

Intended Use of the Device:

ARCHITECT® Anti-Tg is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of the IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma on the ARCHITECT *i* System. The ARCHITECT Anti-Tg assay is intended for use as an aid in the diagnosis of thyroid disease.

The ARCHITECT® Anti-Tg Calibrators are for the calibration of the ARCHITECT® *i* System when used for the quantitative determination of IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma.

The ARCHITECT® Anti-Tg Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT® *i* System (reagents, calibrators and instrument) when used for the quantitative determination of the IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma.

Description of the Device:

The ARCHITECT Anti-Tg assay is a two-step immunoassay for the quantitative determination of the IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex®.

In the first step, sample, assay diluent and Tg coated paramagnetic microparticles are combined and incubated. Anti-Tg present in the sample binds to the Tg coated microparticles. After washing, anti-

human IgG acridinium labeled conjugate is added in the second step. Following another incubation and wash, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLU). A direct relationship exists between the amount of anti-Tg in the sample and the RLUs detected by the ARCHITECT *i* system optics.

8.4 Comparison of Technological Characteristics:

The ARCHITECT® Anti-Tg and the Nichols Advantage Thyroglobulin Autoantibodies assays use a microparticle immunoassay method for the quantitative determination of Anti-Tg in human serum or plasma. Anti-microbial agent is used as a preservative for all reagent components (microparticles and conjugate) of the Nichols Advantage Thyroglobulin Autoantibodies assay as well as the ARCHITECT Anti-Tg. Both assays have magnetic microparticles as the solid support. The ARCHITECT® Anti-Tg and the Nichols Advantage Thyroglobulin Autoantibodies assays both use acridinium labeled conjugates to generate the chemiluminescent in the assay.

8.5 Summary of Non-Clinical Performance:

The ARCHITECT® Anti-Tg assay is substantially equivalent to the Nichols Advantage Thyroglobulin Autoantibodies assay in terms of precision, linearity, interferences, and stability as demonstrated in non-clinical performance data in this 510(k) submission.

8.6 Summary Clinical Performance

The ARCHITECT Anti-Tg assay demonstrated substantially equivalent to the Nichols Advantage Thyroglobulin Autoantibodies Assay. The sample stability study evaluated ARCHITECT Anti-Tg assay using Lithium Heparin and Serum Separator collection tubes. There was no systematic gain or loss of the delectability of Anti-Tg in serum or plasma samples under any of the storage conditions evaluated in this study. A method concordance using the NCCLS Standard (EP-12A) was also conducted with the ARCHITECT Anti-Tg and the Nichols Advantage Thyroglobulin Autoantibodies assays, and as a result, the two systems demonstrated substantial equivalence as indicated by clinical data in this 510(k) submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 10 2006

Fisher Diagnostics
c/o Ms. M. Heather Cameron
Regulatory Compliance Specialist
8365 Valley Pike
P.O. Box 307
Middletown, VA 22645

Re: k052308
Trade/Device Name: ARCHITECT® Anti-Tg , ARCHITECT® Anti-Tg Calibrators and ARCHITECT® Anti-Tg Controls
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid autoantibody immunological test system
Regulatory Class: Class II
Product Code: JZO, JIT, JJX
Dated: August 23, 2005
Received: August 24, 2005

Dear Ms. Cameron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

APPENDICES

8.1 Indications for Use

8.1.1 Reagent Intended Use

ARCHITECT® Anti-Tg is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of the IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma on the ARCHITECT *i* System. The ARCHITECT Anti-Tg assay is intended for use as an aid in the diagnosis of thyroid disease.

8.1.2 Calibrators Intended Use

The ARCHITECT® Anti-Tg Calibrators are for the calibration of the ARCHITECT® *i* System when used for the quantitative determination of IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma.

8.1.3 Controls Intended Use

The ARCHITECT® Anti-Tg Controls are for the estimation of test precision and the detection of systematic analytical deviations of the ARCHITECT® *i* System (reagents, calibrators and instrument) when used for the quantitative determination of the IgG class of thyroglobulin autoantibodies (anti-Tg) in human serum and plasma.

510 (k) Number (if known): K# 052308

Device Name: ARCHITECT® Anti-Tg Immunoassay, ARCHITECT® Anti-Tg Calibrators & Controls

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K052308